

**OFFICE OF SPECIAL MASTERS**

(E-Filed: September 5, 2006)

No. 99-544V

UNPUBLISHED

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BRANDON TURNER,	)	
	)	
	)	
Petitioner,	)	
	)	
v.	)	Motion for Judgment on the
	)	Record; Failure to Offer Medical
	)	or Expert Opinion Supporting
SECRETARY OF THE DEPARTMENT OF	)	Causation Claim
HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	
	)	
	)	

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Clifford John Shoemaker, Vienna, VA, for Petitioner.

Vincent James Matanoski, U.S. Department of Justice, Washington, DC, for Respondent.

**DECISION**<sup>1</sup>

On July 29, 1999, petitioner, Nancy Turner, as Guardian ad Litem for Brandon

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<sup>1</sup> Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless an issued decision contains trade secrets or commercial or financial information that is privileged or confidential, or the decision contains medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. When a special master files a decision or substantive order with the Clerk of the Court, each party has 14 days within which to identify and move for the redaction of privileged or confidential information before the document's public disclosure.

Turner (Brandon), a minor,<sup>2</sup> filed a petition pursuant to the National Vaccine Injury Compensation Program<sup>3</sup> (the Act or the Program). The petition alleges that “[o]n or about February 12, 1993, March 18, 1993, and August 16, 1993, Petitioner received hepatitis B vaccination(s) (a vaccine set forth in the Vaccine Injury Table) in the United States and experienced an adverse reaction to this (these) inoculation(s).” See Petition (Petn.), filed July 29, 1999. The petition does not describe the specific injury alleged to have resulted from Brandon’s hepatitis B vaccinations.<sup>4</sup> The filed medical records include Brandon’s immunization records, a Vaccine Adverse Event Reporting System (“VAERS”)<sup>5</sup> report filed by Brandon’s mother, and medical records addressing the treatment Brandon received for a benign mass detected in his left testicle, which appears to be the alleged injury resulting from the hepatitis B vaccinations. Other than the VAERS report filed by Brandon’s mother, there is no evidence in the record before the court to support the allegation that the hepatitis B vaccination caused Brandon’s injury.

On June 22, 2006, petitioner’s counsel filed a Motion for Judgment on the Record “as it stands.” (P’s Mot. at 1). The record in this case consists of the petition and five sets of medical records. Petitioner’s brief motion requests judgment on the record because “petitioner does not feel that he can prove causation, as he cannot find an expert to support

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<sup>2</sup> On June 22, 2006, petitioner filed a Motion to Amend Caption. On June 28, 2006, the Special Master granted petitioner’s Motion to Amend Caption. Brandon Turner is currently the sole petitioner in this case because he is no longer a minor.

<sup>3</sup> The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

<sup>4</sup> The hepatitis B vaccine is “a noninfectious viral vaccine derived by recombination from hepatitis B surface antigen and cloned in yeast cells; administered intramuscularly for immunization of children and adolescents and of persons at increased risk for infection.” Dorland’s Illustrated Medical Dictionary 1999 (30th ed. 2003).

<sup>5</sup> VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify new and important safety concerns and thereby assists in ensuring that the benefits of vaccines continue to outweigh the risks. See Frequently Asked Questions About VAERS, at <http://vaers.hhs.gov/vaers.htm> (last visited August 30, 2006). Any person can file a report with VAERS. Id. The filing of a VAERS report does not constitute a determination that a vaccination has caused an injury.

causation in his case.” Id.

On June 30, 2006, respondent filed Respondent’s Response to Petitioner’s Motion for Judgment on the Record (R’s Response). Respondent does not object to the motion or the entry of a decision in this case. In its response, respondent states that petitioner “[p]rovided no evidence—neither medical records nor medical opinion—to support his allegation that the hepatitis B vaccination caused his alleged injuries, and thus failed to support his claim as required by law.” R’s Response at R-2 (citing 42 U.S.C. § 300aa-13(a)(1)(“The special master or court may not make [a finding for petitioner] based on the claims of petitioner alone, unsubstantiated by medical records or by medical opinion.”)).

Petitioner’s motion for judgment on the record is now ripe for decision.

## **I. Facts**

Brandon was born on April 3, 1978. Petitioner’s Exhibit (P’s Ex.) 1 at 4. On February 12, 1993, March 18, 1993, and August 16, 1993, Brandon received the hepatitis B vaccination. P’s Ex. 1 at 21. On December 18, 1997, Dr. Timothy C. Hlavinka, M.D., Diplomate, American Board of Urology, evaluated Brandon. Dr. Hlavinka wrote in the patient history section of his notes that Brandon “noted a hard non-enlarging not tender hemiscrotal mass two months ago.” P’s Ex. 2 at 9. On December 23, following a left radical orchiectomy<sup>6</sup> that removed a benign fibrotic and inflammatory mass, Dr. Hlavinka noted that “this is an unusual tumor of the testicle and of unclear etiology.” P’s Ex. 2 at 19. Dr. Hlavinka attributed causation to “an unnoticed trauma” Id.

Brandon’s records also indicate that on or about May 29, 1998, his mother filed a VAERS Report. P’s Ex. 4 at 3. She reported that Brandon had suffered a “testis disorder,” a “collagen disorder,”<sup>7</sup> and a “neoplasm”<sup>8</sup> as a result of his hepatitis B vaccinations. Id.

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<sup>6</sup>An orchiectomy is “excision of one or both testes.” Dorland’s Illustrated Medical Dictionary 1321 (30th ed. 2003).

<sup>7</sup>A collagen disorder is “any inborn error of metabolism involving abnormal structure or metabolism of collagen.” Dorland’s Illustrated Medical Dictionary 548 (30th ed. 2003). Collagen is “any of a family of extracellular, closely related proteins occurring as major components of connective tissue, giving it strength and flexibility.” Id. at 388.

<sup>8</sup>A neoplasm is “any new and abnormal growth; specifically a new growth of tissue in which the growth is uncontrolled and progressive.” Dorland’s Illustrated Medical Dictionary 1228 (30th ed. 2003).

Petitioner has not filed any medical opinion or any medical literature or offered any expert testimony supporting a causal link between his receipt of the hepatitis B vaccination and his development of a benign fibrotic mass of the tunica albuginea.<sup>9</sup> Furthermore, this “unusual” development occurred four years after Brandon’s receipt of the hepatitis B vaccinations.

## **II. Discussion**

Before the court is a motion for judgment on the record “as it stands.” P’s Mot. at 1. Brandon’s filed medical records indicate that he sought treatment for a benign mass located in his left testicle. Absent evidence of another medical condition for which Brandon sought treatment, the undersigned considers the diagnosed mass in Brandon’s left testicle to be the injury alleged to have resulted from petitioner’s hepatitis B vaccinations. This determination is supported by the VAERS report filed by Brandon’s mother in May 1998, alleging that Brandon suffered a testis disorder as a result of his hepatitis B vaccination.

The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Because a testicular mass is not an injury listed on the Vaccine Injury Table, Brandon does not benefit from the Act’s presumed causation. Id. Thus, petitioner must prove that the vaccines in-fact caused his injury, a so-called “off-Table” case.

To demonstrate entitlement to compensation in an off-Table case, petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To satisfy his burden of proof, petitioner must show:

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274,1278 (Fed. Cir. 2005) (Althen III). See also Grant, 956 F.2d at 1148 (petitioner must show “a medical theory causally connecting the

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<sup>9</sup>A tunica albuginea is a “white coat; a dense, white, fibrous sheath enclosing a part or organ.” Dorland’s Illustrated Medical Dictionary 1972 (30th ed. 2003).

vaccination and the injury”)(citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). A logical sequence of cause and effect requires support of “[a] reputable medical or scientific explanation” which may be “evidence in the form of scientific studies or expert medical testimony.”<sup>10</sup> Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Circumstantial evidence and the medical opinions of treating physicians or other experts may also be sufficient to establish a logical cause and effect. See Capizzano v. Secretary, 440 F.3d 1317, 1325 (Fed. Cir. 2006).

In this case, petitioner does not satisfy a single prong of the showing required in Althen III. Other than the VAERS report filed by his mother, petitioner has supplied no evidence connecting his hepatitis B vaccinations to his injury. Petitioner offers no expert

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<sup>10</sup>The general acceptance of a theory within the scientific community may bear positively on an assessment of theory’s reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that the guidance in “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, the scientific method must be applied to validate an expert’s opinion. Id. Factors that support validation of an expert’s opinion may include, but are not limited to:

Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

opinion causally connecting the vaccination to his injury. Petitioner offers no medical or scientific explanation to substantiate his claim of cause and effect. Nor does petitioner establish a proximate temporal relationship between his vaccination and his injury. Petitioner has not satisfied his burden of proving his claim.

### **III. CONCLUSION**

Petitioner has failed to substantiate his claims of causation with either medical records or a medical opinion, and petitioner has conceded that he “cannot find an expert to support causation in this case.” Because he is unable to produce any evidence that the hepatitis B vaccinations caused his injury, petitioner has failed to establish his entitlement to compensation under the Vaccine Act. The court dismisses this case for want of proof. The Clerk of the Court shall enter judgment accordingly.<sup>11</sup>

**IT IS SO ORDERED.**

s/Patricia E. Campbell-Smith  
Patricia E. Campbell-Smith  
Special Master

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<sup>11</sup>Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties’ joint filing of notice renouncing the right to seek review.